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Long-term Outcomes and Complications of Metallic Stents for Malignant Esophageal Stenoses

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Thirty patients with malignant esophageal stenosis underwent Ultraflex esophageal stent deployment and were followed up for a maximum of 29 months from June 1995 to August 2001 in Tenri Hospital. Twelve stents were in the upper esophagus, and nine each in the middle and lower esophagus. The procedures were successful and dysphagia scores improved from 2.9 to 0.7. Major complications such as esophagorespiratory fistula, hematemesis, or airway compression occurred in 9 patients, more often in the upper esophagus than in other parts of the esophagus, with no statistical difference. There was a significant difference in the onset of major complications between the upper and middle esophagus, as well as between the upper and middle-lower esophagus ($p<0.05$), but no difference in mean survival time between locations, or patients with or without major complications.

These results demonstrate that esophageal stent deployment is effective for relieving dysphagia and associating malnutrition. But major complications may occur in the upper esophagus more often and earlier than in other parts.

Metallic stents are effective in relieving those patients with malignant esophageal stenosis from their suffering from dysphagia and malnutrition. On the other hand, several serious complications after the stent deployment or during the long-term follow up have been described in the literature, which include massive bleeding, tracheal compression, esophagorespiratory fistula, and esophageal compression[1-10]. Of commercially available esophageal stents, the Ultraflex (Boston Scientific Inc. USA), a knitted nitinol stent, is so flexible and secure that the esophageal wall is not excessively compressed while the lumen is kept patent [11, 12]. In this study, we used Ultraflex stents in 30 patients with malignant esophageal stenoses or fistulas, and evaluated the therapeutic effects, complications, long-term outcomes, and prognosis.

MATERIALS AND METHODS

From June 1995 to August 2001, 30 patients with malignant esophageal stenoses, including 24 men and 6 women aged 46-86 years (mean 69.4 years), underwent esophageal stent deployment with covered or bare Ultraflex stent in Tenri hospital. Twenty-nine patients were observed until their final outcomes or death for a maximum of 29 months, while one patient is alive and has been followed up. Subjects consist of 20 patients with esophageal cancer, 7 patients with infiltrative lung cancer, 2 patients with mediastinal metastasis from breast cancer, and one patient with esophageal infiltration from gastric cancer. The location of stenosis or fistula was in the upper esophagus in 12 patients, the middle esophagus in 9

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patients, and the lower esophagus in 9 patients. The length of stenosis ranged from 2.0 to 12.0 cm (mean 6.3cm) (Table 1). The protocol or indication of esophageal stents in our institution is so strict that stent deployment is confined to the relief of patients with recurring

Table 1. Patients' background

Levels (n)	Causes		Length of stenosis / Mean (cm)
Upper (12)	Esophageal cancer	6	3.0 - 10.0 / 6.3
	Lung cancer	5	
	Breast cancer	1	
Middle (9)	Esophageal cancer	7	3.0 - 8.0 / 5.5
	Lung cancer	2	
Lower (9)	Esophageal cancer	7	2.0 - 12.0 / 7.7
	Gastric cancer	1	
	Breast cancer	1	
Total		30	2.0 - 12.0 / 6.3

dysphagia or mediastinal fistula who previously had anti-cancer therapies such as chemotherapy or irradiation. That is the reason why the number of subjects is so small for the period of study. Twenty-seven patients (90.0 %) had irradiation therapy and 20 patients (66.7 %) had systemic chemotherapy prior to the stent deployment. Eight patients (26.7 %) had esophageal stenoses with fistulous lesions: esophagorespiratory fistulas in 5 patients (16.7 %) including esophagotracheal, esophagobronchial and esophagopulmonary fistulas, as well as esophagomediastinal fistulas in 3 patients (10.0%). To one patient with esophageal and bronchial stenosis resulting from mediastinal infiltration of lung cancer, a Z-stent (Cook Inc. USA) was placed to the left main bronchus prior to the esophageal stent deployment. The procedure was performed with an angiographic fluoroscopic unit (Angiostar Plus, Siemens Inc. Germany) equipped with a C-arm. While the patient lay on a tabletop, a 5 Fr straight catheter was negotiated to pass the esophageal stenosis down to the stomach using a 0.035-inch Radifocus guidewire (Terumo Inc. Japan). After the length of stenosis was decided with endoscopy or contrast material injection through the catheter, the range of stent deployment was set down with use of a fluoroscopic marker, a Wire Marker Board (Cook Inc, USA), placed underneath the patient. Stenotic lesions were usually predilated with a balloon catheter (Boston scientific Inc. USA) and a 0.035-inch Amplatz super-stiff guidewire. A large diameter (15 to 20 mm-wide) balloon catheter was utilized in order to find out acute airway compression or hypoxia [13]. During the balloon predilatation, the patients were observed in terms of their respiration and oxygen saturation with a pulse-oxymeter attached at the fingertip for several minutes. The covered Ultraflex stent was basically chosen because it is advantageous for preventing tumor ingrowth and sealing fistulas. However, the bare Ultraflex was chosen in 7 patients with stenotic lesion across the cardia to avoid migration. The patients were evaluated by scoring dysphagia scores into five categories: swallowing normal diet (Score 0), swallowing solids (Score 1), swallowing semi-solids (Score 2), swallowing liquids only (Score 3), and not swallowing even liquids (Score 4). Scores were counted before the stent deployment and a week after that. Thereafter, the patients were

followed up once a month on an outpatient basis, questioned about their swallowing and food intake, and sometimes asked to take an endoscopy, barium study, or computed tomography in order to evaluate esophageal passages.

Both survival time of the patients and onset of complications after the stent deployment were calculated with a Kaplan-Meier method. Each subgroup was estimated with a log-rank test, and the difference was judged as statistically significant if the P-value was less than 0.05. The incidence of major complications in each esophageal level was compared with a chi-square test and Fisher's exact probability test.

RESULTS

Esophageal Stent Deployment

The deployment of esophageal stents was technically successful in all patients. No patients showed dyspnea or lowered oxygen saturation during the balloon predilatation or stent deployment. Twenty-four covered Ultraflex stents, including seventeen 10cm-long / 7cm-covered / 17mm-wide stents, one 10cm-long / 7cm-covered / 22mm-wide stent, and six 15cm-long / 12cm-covered / 17mm-wide stents, were deployed in 23 patients; on the other hand, eight bare Ultraflex stents, including three 7cm-long / 18mm-wide stents, three 10cm-long / 18mm-wide stents, and two 15cm-long / 18mm-wide stents, were deployed in seven patients. One of the patients with lower esophageal 12cm-long stenosis needed two units of 15cm-long / 12cm-covered / 18mm-wide stent and 10cm-long / 7cm-covered / 18mm-wide stent to cover an entire length of stenosis. Another patient with lower esophageal 10cm-long stenosis needed two units of 7cm-long / 17mm-wide bare stent, because a single 15cm-long / 17mm-wide bare stent was difficult to convey beyond the stenosis. In a particular patient with cervical esophageal stenosis and tracheal fistula very close to the cricoid pharyngeal muscle, a modified inverted Ultraflex covered with polyurethane by a dipping method [14, 15] (Figure 1) was utilized to seal the fistula and prevent the cricoid pharyngeal muscle from being stented and compressed by a flared portion of the stent.

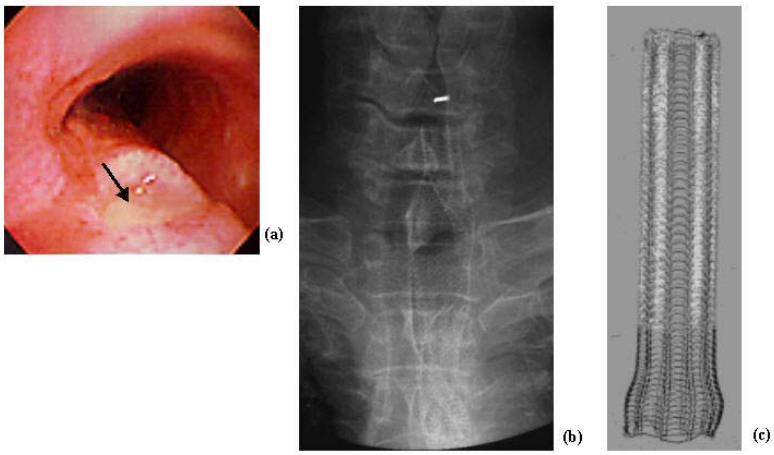

Figure 1. A 71-year-old man with cervical esophageal cancer and esophagotracheal fistula, as shown on an endoscopic view (a, arrow), was referred for the stent deployment. The fistula was so close to the cricoid pharyngeal muscle (b, lead marker) that a custom-made, inverted, and polyurethane-covered Ultraflex stent (c) was successfully utilized.

Dysphagia Scores

As a result of dilated esophageal lumen and obliterated fistula, 29 patients improved their dysphagia scores from 2.9 to 0.7 on average after the stent deployment, although one patient died from fatal hemoptysis two days after the stent deployment. More precisely, in each level of the esophagus, dysphagia scores lowered from 3.7 to 0.3 in the upper esophagus (11 patients), from 2.9 to 0.9 in the middle esophagus (9 patients), and from 2.8 to 1.1 in the lower esophagus (9 patients), respectively (Table 2). Two patients did not improve their scores, but increased their oral intake after the stent deployment. The effect of initial treatment generally lasted from 8 to 671 days (mean 128.5 days, median: 78 days).

Table 2. Dysphagia scores before and after stent deployment in each location of esophagus

	Upper (n=11*)		Middle (9)		Lower (9)	
	Before	After	Before	After	Before	After
Score 0	-	9	-	2	-	3
Score 1	-	1	-	6	1	3
Score 2	3	1	2	1	1	2
Score 3	5	-	6	-	6	1
Score 4	3	-	1	-	1	-
Mean score	3.7	0.3	2.9	0.9	2.8	1.1

*One patient was dead before the evaluation.

Minor Complications

Most patients complained of mild foreign body sensation or pain immediately after the stent deployment, but a week later, they were getting better and free of these symptoms. Nine patients (30 %) showed re-obstruction of esophageal stents during the follow-up, the causes of which consisted of food impaction, mucosal hyperplasia, tumor overgrowth, migration, pocket formation, and incomplete stent dilatation. The incidence of re-obstruction was 33.3 % in the upper esophagus, 11.1 % in the middle esophagus, and 44.4 % in the lower esophagus, respectively (Table 3). To overcome re-obstruction, two patients with mucosal

Table 3. Re-obstruction after stent deployment

	Food impaction	Mucosal hyperplasia	Incomplete dilation	Pocket formation	Overgrowth	Migration	Total
Upper (n=12)	3	-	-	-	1*	-	4 (33.3%)
Onset (Days)	17 20 75				89		
Middle (9)	-	1	-	-	-	-	1 (11.1%)
		269					
Lower (9)	-	1	1	1*	-	1*	4 (44.4%)
		478	9	99		90	

* No re-intervention

hyperplasia underwent additional stent deployment, and one patient with incomplete stent dilatation took balloon dilation again. Three patients with food impaction undertook endoscopic water cleansing inside the stent lumen. Because of deteriorated general conditions, each patient with stent migration, tumor overgrowth, and pocket formation was observed without secondary interventions.

Major Complications

Nine of 30 patients (30.0 %) showed major complications such as fistula formation, massive fatal hemoptysis, hematemesis, or tracheal compression causing dyspnea or stridor (Table 4). In detail, in the upper esophagus, 6 of 12 patients (50.0 %) encountered esophagotracheal fistula formation (Figure 2), massive fatal hemoptysis, or tracheal

Table 4. Onset of major complications after stent deployment

	Fistula formation	Tracheal compression	Hemoptysis	Hematemesis	Total
Upper (n=12)	3	1	2	-	6 (50.0%)
Onset / Death (Days)	46 / 69 96 / 125 170 / 543*	14 / 33	2 / 2 22 / 22		
Middle (9)	1	-	-	1	2 (22.2%)
	324 / 325			269 / 351	
Lower (9)	-	-	-	1	1 (11.1%)
				62 / 81	

*Alive with the additional stent deployment.

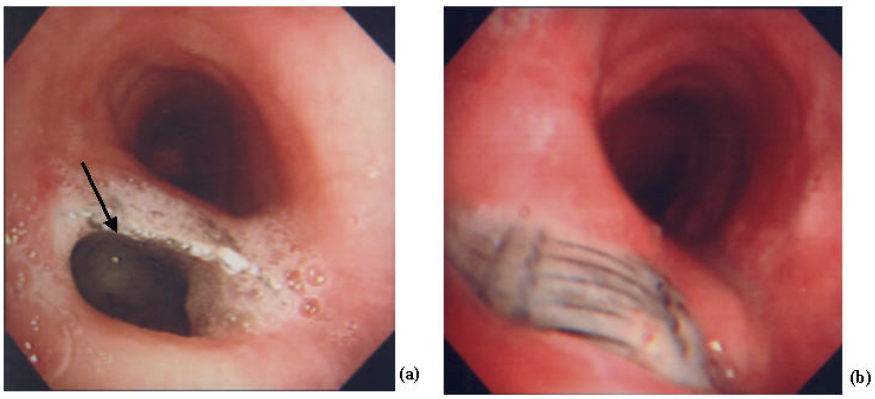

Figure 2. A 60-year-old man with esophageal cancer, previously treated with chemo-irradiation therapy and bare Ultraflex stent, suffered with esophagotracheal fistula resulting from the protrusion of stent edge to the trachea, as shown on an endoscopic view (a, arrow). The covered Ultraflex was additionally deployed for the sealing of fistula (b).

compression (Figure 3). In the middle esophagus, 2 of 9 patients (22.2 %) had pericardial fistula or hematemesis, and then in the lower esophagus, 1 of 9 patients (11.1%) presented hematemesis. Although there was no significant difference in the incidence of major complications between each two locations of the stent, major complications tended to occur at a higher rate in the upper esophagus than in other parts of the esophagus. The complications generally took place within 2 to 324 days (mean 111.7 days) after the stent deployment; in each location, they occurred within 2 to 170 days (mean 58.3 days) in the upper esophagus, 269 to 324 days (mean 296.5days) in the middle esophagus, and 62 days in the lower esophagus, respectively. There was a significant difference in the onset of major complications between in the upper esophagus and the middle esophagus ($p<0.05$), as well as between in the upper esophagus and the middle-lower esophagus ($p<0.05$ (Figure 4).

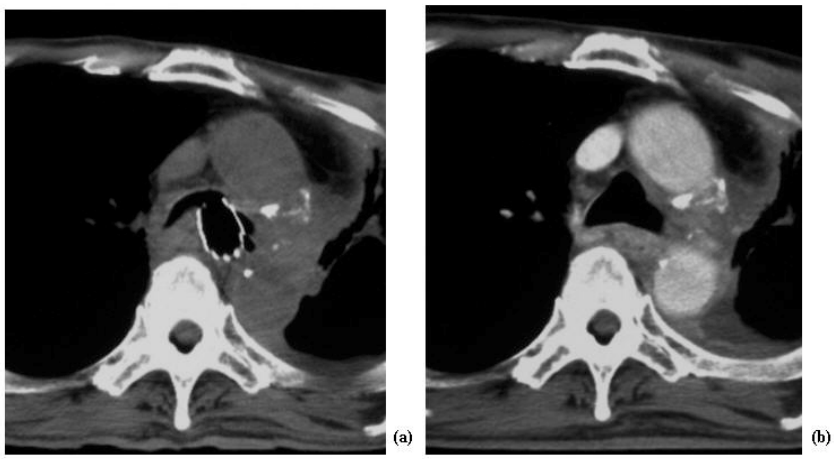

Figure 3. A58-year-old men with residual lung cancer after chemo-irradiation therapy. Computed tomography before stent deployment shows no tracheal stenosis (a). Follow up CT (75days after stent deployment) shows severe tracheal compression due to esophageal stent (b).

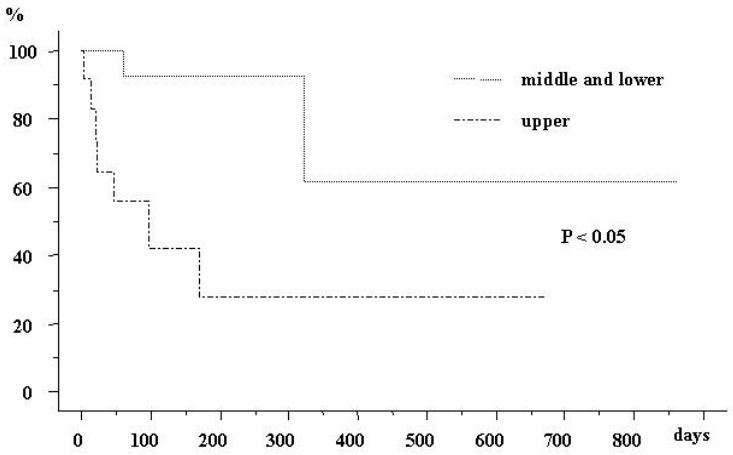

Figure 4. Onset of major complications (upper vs. middle and lower)

Unfortunately, 3 of 6 patients who had the stent deployment in the upper esophagus suffered from hemoptysis or tracheal compression within 30 days (mean 12.7days), and they eventually died on the same day or within three weeks after these life-threatening complications. Major complications were mostly life-threatening because the patients died of these unfavorable events relevant to the stent deployment, and in addition, they had no helpful means to recover from such troublesome situations. However, as shown in a particular case of stent-related fistula (Figure 2), the patient has recovered well with the use of an additional covered Ultraflex stent. Other patients were treated palliatively because of too advanced diseases and poor general conditions.

Long-term Outcomes and Prognosis

In a follow up of the patients until their final outcomes, 29 patients died in 2 to 864 days (mean 178.8 days, median: 81.5 days) after the stent deployment, but one patient (Figure 2) has been alive and well for 543 days. The mean survival time was 182.8 days (median: 65 days) in the upper esophagus, 247.7 days (median: 179 days) in the middle esophagus and 142.2 days (median: 81 days) in lower esophagus, with no significant difference between each two groups of stent locations. The mean survival time was 112.0 days (median: 54 days) in patients with major complications and 207.0 days (median: 86 days) in patients without major complications, with no significant difference between two groups of patients (Figure 5).

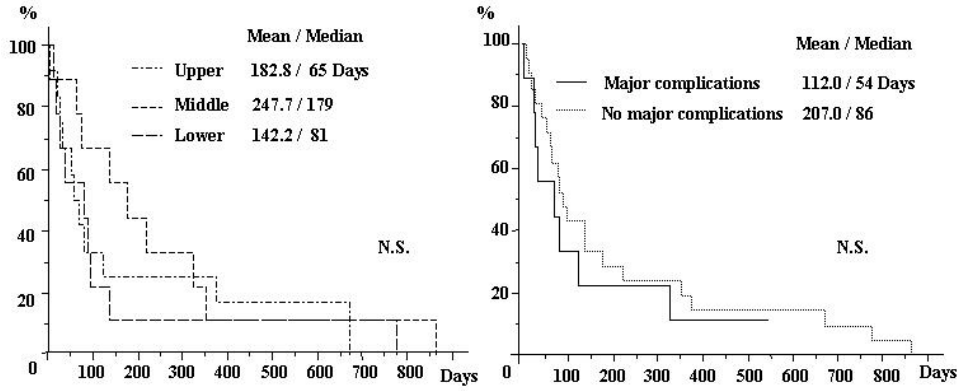

Figure 5. Survival time curves of the patients: Locations and major complications

DISCUSSION

Deployment of esophageal metallic stents has acquired popularity in the treatment of esophageal malignant stenosis, leading to several advantages in a smaller caliber delivery system and wider reconstructed lumen of the esophagus than with conventional esophageal tube stents. Later on, in association with esophageal metallic stents, major or life-threatening complications such as hemorrhages, esophagorespiratory fistulas, tracheo-bronchial compression, and esophageal ruptures were reported in the literature[1)-10)]. Kinsman, et al.[16)] reported that irradiation therapy and chemotherapy prior to stent deployment could induce esophagitis, ulceration, submucosal fibrosis and angitis, and possibly provoke risks of major complications. Cwikiel, et al. [17)] described in their experimental animal studies and case reports that esophageal metallic stents cause pressure necrosis, inflammation, and subsequent fibrosis in the esophageal wall, which may predispose the pathological processes triggering

serious complications. Moreover, it is well known that too large or rigid stents also promote pressure necrosis for the same reason. The Ultraflex stent is one of the self-expandable metallic stents most flexible and available in gastrointestinal strictures [18], even to tortuous or kinked lesions[11, 12]. Schmassmann et al. [10] reported that procedure-related mortality and severe persistent pain were frequent in bare Wallstent compared with bare Ultraflex. On the other hand, Dorta et al. [19] reported that incomplete dilation in the bare Ultraflex stent was frequent because of its insufficient expanding force compared with bare Wallstent. But Covered Ultraflex stent we mainly used has silicone membrane that contributes to intensify the expanding force and to decrease the risk of stent-related fistula formation. Siersema et al [9] reported major complication of covered Ultraflex stent and Flamingo Wallstent were lower than that of Gianturco-Z stent. However, there are several reports [18, 20, 21] of Ultraflex stents and major complications taking place in a long-term follow up of the patients. Wang, et al. [21] described the possibilities of delayed complications relevant to stent deployment in the long-term follow up, including major complications such as esophagotracheal fistulas, massive fatal hemoptysis, or significant tracheobronchial compression. They added that the complication was significantly lower in Ultraflex stents than in Z-stents or Wallstents and the incidence was higher in the upper esophagus. Our study suggests that even most flexible Ultraflex stents provoke such complications, often in the upper esophagus. The reason for major complications in the upper esophagus must be anatomical parallelism to each other throughout their courses and tracheobronchial configuration of a stiff cartilage portion and soft membranous portion. Between the esophageal wall that has no serosa and a tracheal membranous portion, there exist no definite boundaries resistant to a self-expanding force of the stent deployed into the esophagus, thus possibly contributing to airway compression. Especially when deployed in a sandwich pattern between the vertebra and trachea, the expanding force will be directed to the weaker membranous portion of the trachea, likely promoting pressure necrosis and esophagotracheal perforation for the time being. In addition to the anatomical characteristics of the upper esophagus, both voluntary physical movements of the cervix and swallowing motions of the sphincter muscles would impose an excessive tension or stress on the extended esophageal wall. Our experiences suggest that the esophageal segment touched over the flared upper edge of Ultraflex stent is very vulnerable to esophagotracheal fistulas. The lower edge of Ultraflex stent on tracheal bifurcation is another spot susceptible to fistula formation. Pre-deployment CT observation on anatomical relationships between the tracheobronchial lumen and vertebrae would be helpful to understand the direction of expanding forces of the stent and to make a prediction of potential major complications.

Our study of the esophageal stent deployment in 30 patients with malignant stenosis, done with the use of single type of Ultraflex stents and mostly completed in the follow-up of the patients, seems very unique, because there are no other studies in the literature based on the homogenous background of patients and methods utilized in the study. As mentioned above, esophageal metallic stents are effective in relieving patients with malignant stenosis from dysphagia and malnutrition; however, it should be taken into account that they also possibly provoke several complications during the follow-up of the patients, even in the use of Ultraflex. In addition, stent-related airway complications may occur in the upper esophagus at a higher rate and earlier after stent deployment than in other parts of the esophagus. To cope with potential complications of esophagorespiratory fistulas, the use of covered Ultraflex stents is recommended in the upper esophagus. More importantly, it is necessary to explain to the patient about probable side effects of esophageal stents as well as their therapeutic effects when obtaining a consent for the treatment, and it is also rewarding

to closely monitor the patients after the stent deployment, as represented in the successful patient who has overcome stent-related esophagorespiratory fistula by overlapping another covered Ultraflex, leading to his longer survival. Our study shows no significant difference in the mean survival time among several confined groups of patients, which may stem from the small number of subjects studied, and mostly from the background of patients who have recurrent and refractory malignant tumors. To the patients in such a difficult situation, dysphagia and associating malnutrition are so critical, we believe, that the esophageal stent deployment continues to be helpful; however, we have to be more knowledgeable about deciding the indication and judging the trade-off of esophageal metallic stents.

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